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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,878	09/03/2002	Douglas Rees	16230-8446	1525

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,878	REES, DOUGLAS	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending and are considered on the merits.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 4, 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 states that sodium, potassium, calcium and magnesium ions are chloride salts, but the that only 118.4 mmoles/L of chloride ion is present in the solution. However, 135.32 mmoles/L are present simply as the chloride ion of the sodium salt. Please cancel "as chloride salts".

Claim 8 is confusing because the terminology has changed from the terminology in claim 1. According to CAS Registry thiamine pyrophosphate chloride is also called cocarboxylase. Please restate to say 40.0mmoles/L thiamine pyrophosphate chloride in claim 8 and thiamine pyrophosphate chloride in claim 1 instead of thiamine cocarboxylase. See attached CAS Registry listing.

Claim 9 states that 50.0 gmoles/l of L-carnitine is present. However, the independent claim has a range of 40-70 micromoles/L. Please correct gmoles to μmoles/L.

Claim 10 has in parenthesis (expressed in E. coli). It cannot be understood if this is a further limitation. Please cancel the phrase.

Claim 11 misspells dichloroacetamide.

Claim 12 states that thiamine is added to the mixture. There is NO thiamine in claim 1. There is thiamine pyrophosphate chloride which is a distinct compound from thiamine.

Use of a constant style is suggested. For example, commas should be placed after glucose and glycerol in (iii)(h) (i). Commas should be placed after glutamate and aspartate in (iv) (k)(l). Claim 1 should end with a period not ";and".

Dependent claims should begin with "The".

Claim 2 should state "which further comprises".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-10, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parr *et al.* [U] in view of Clements *et al.* [V].

The claims are directed to a solution containing:

(i) 100-150mM Na^{+},
2.5-6.2mM K^{+},
0.1-2.5mM Ca^{+2},
0.4-25mM Mg^{+2},
96-126mM Cl^{-};

(ii) 21-27mM bicarbonate ions,
1-12mM TES or MOPS or BES;

(iii) 2-11mM glucose,
50-150μM glycerol,
7-15μM choline;

(iv) 5-400μM glutamate,
5-200μM aspartate,
100-2000μM glutamine;

(v) 1-120nM thiamine cocarboxylase;

(vi) 40-70μM D or L or DL-carnitine;

(vii) 5-200mIU/l porcine or human insulin.

The references are relied upon as explained below.

Parr *et al.* in Table 1 disclose a solution for perfusing and immersing tissues/organs comprising :

(i) 136mM Na^+,
5mM K^+,
1.2mM Ca^{+2},
0.45mM Mg^{+2},
118mM Cl^-;

(ii) 25mM bicarbonate ions,
5mM BES;

(iii) 10mM glucose,
110μM glycerol,
10μM choline;

(iv) 300μM glutamate,

20μM aspartate,
400μM glutamine;

(v) 430μM thiamine cocarboxylase;

(vi) 50μM DL-carnitine;

(vii) 25mIU/l porcine insulin.

The primary reference of Parr *et al.* lacks the specific concentration of TTP (v) in the claimed solution in that the concentration of TTP is lower in the claimed solution.

Clements *et al.* disclose a solution for perfusing and immersing tissues/organs which uses as a component, TTP in a concentration of 40nM (Table 2).

The substitution of a lower concentration of TTP in the area of 40nM in the solution of Parr *et al.* would have been obvious when the disclosure of Clements *et al.* was taken with the primary reference because such a concentration has been used in the prior art in tissue and organ preservation solutions.

MPEP 2144.05 II. A. states that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical.

Claim 9 is interpreted to mean that 50microM of L-carnitine is a component of the solution.

The primary reference of Parr *et al.* disclose the use of 50microM DL-carnitine as a component of the solution. In the absence of evidence to the contrary, the same concentration of DL carnitine is reasonably assumed to have

the same effect as 50microM L-carnitine in a solution used to perfuse and immerse tissues/organs.

Claim 10 has 28mIU/L of recombinant human insulin as the insulin component of the solution.

Parr *et al.* disclose the use of 25mIU/L of porcine insulin as the insulin component of the solution.

In the absence of evidence to the contrary, human insulin and porcine insulin are considered to be functional equivalents in solutions used to preserve organs/tissue, particularly since the solution may be tailored for the source of the organ. That is, one of skill in the art using a solution to perfuse a human organ, may prefer to use human insulin instead of porcine insulin. In the absence of criticality, this is considered to be an element of experimental design well within the purview of one of skill in the art.

Claim 12 is directed to a mixing the components of claim 1 in a particular order.

MPEP 2144.04 IV. C cites *In re Gibson*, 39 F.2d 975, 5 USPQ (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious).

Claims 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Parr *et al.* and Clements *et al.* as applied to claims 1, 3-10, 12-14 above, and further in view of the Gibco Catalog [W].

Claims 13 and 14 are directed to concentrates for the preparation of the medium of claim 1. Concentrates in the art of media preparation are well known. Also routine in the art is the separation of the bicarbonate buffer for the rest of the ingredients. See Gibco Catalog, page 72, where the production of 1X solutions of media and balanced salt solutions from 10X concentrates of various media and separate bicarbonate solutions are discussed.

Claims 2 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Parr *et al.* and Clements *et al.* as applied to claims 1, 3-10, 12-14 above, and further in view of Rees *et al.* [X].

Claim 2 is further directed to the addition of 10-150mg/L chloramphenicol to the solution.

Claim 11 includes 100mg/L chloramphenicol in the solution.

Rees *et al.* disclose the addition of 50mg/l chloramphenicol to a solution used to perfuse and immerse organs.

The inclusion of 100mg/L of chloramphenicol in the solution is well within the purview of one of ordinary skill in the art, particularly with regard to the prior art usage of 50mg/L chloramphenicol.

MPEP 2144.05 II. A. states that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See *In re Aller*, 220 F.2d 454,456,105USPQ 233,235(CCPA 1955).

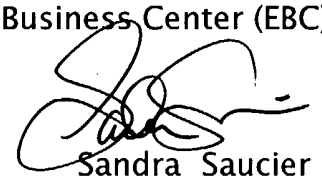
The addition of an antibiotic, in particular chloramphenicol to the solution disclosed by Parr *et al.* and Clements *et al.* would have been obvious when taken with Rees *et al.* because such an addition has been made to solutions used for perfusion of organs in the prior art.

One of ordinary skill in the art would have been motivated at the time of invention to make this addition in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651